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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,050	05/17/2001	Hidetoshi Uemura	UEMURA 8	4088

1444 7590 08/12/2003

BROWDY AND NEIMARK, P.L.L.C.  
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WASHINGTON, DC 20001-5303

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/12/2003

) )

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/856,050

Applicant(s)

UEMURA ET AL.

Examin r

David J Steadman

Art Unit

1652

-- The MAILING DATE of this communication appears n th cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

**DETAILED ACTION**

***Status of the Application***

- [1]** Claims 1-29 are pending in the application.
- [2]** Applicant's amendment to the specification in Paper No. 6, filed May 17, 2001, is acknowledged.
- [3]** Applicant's amendment to the specification, amendment to claims 3, 4, 6, 7, 9-14, 18, 20, and 22-24, and addition of claims 25-29 in Paper No. 7, filed May 17, 2001, is acknowledged.
- [4]** Applicant's amendment to the specification and amendment to claims 5 and 8 in Paper No. 8, filed May 17, 2001, is acknowledged.
- [5]** It is noted that the instant application has been transferred to Art Unit 1652. Applicant asserts the previous examiner contacted applicant for a telephonic restriction (see the communication of Paper No. 9). In the claim groupings presented to applicant during this telephonic restriction, claims 25-29 were not included. In the interest of clarifying the record, the following supplemental restriction is provided.

***Lack of Unity***

- [6]** Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

**Group I**, claims 1-18, 20, 25, and 27, drawn to the special technical feature of a protein expression vector and a host cell comprising said expression vector and the first claimed method of use, i.e., a process for producing a target protein using a protein expression vector or host cell.

**Group II**, claims 19, 21, 24, 26, 28, and 29, drawn to a target protein and a recombinant fusion protein.

**Group III**, claims 22 and 23, drawn to a process for producing a target protein by cleaving a recombinant fusion protein to release a target protein.

Art Unit: 1652

**[7]** The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

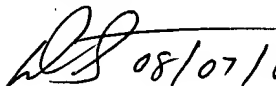
According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions of Groups I-III do not relate to a single general inventive concept because the shared same or corresponding technical features of Groups I-III are not contributions over the prior art. The technical feature of Group I is a protein expression vector, which is shown by New England Biolabs 1995 Catalog (pages 140-141) to lack novelty or inventive step because New England Biolabs 1995 Catalog (pages 140-141) teach a protein expression vector (pMAL-p2) comprising a nucleotide sequence encoding a malE signal sequence, an MBP tag, a Factor Xa cleavage site, and a polycloning site for insertion of a protein-encoding sequence of interest. Therefore, the technical feature of Group I does not make it a contribution over the prior art.

**[8]** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

**[9]** Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner  
Art Unit 1652



08/07/03